

IV. Robust Summaries of Existing Data

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil
CAS #	8002-26-4
Remarks	This substance is referred to as tall oil in the test plan for tall oil and related substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Tall oil was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. As a reference substance, a mixture of seven materials was used.
<u>Results</u>	At pH 2, the log P _{ow} [K _{ow}] values of eight components in tall oil were 6.1, 6.5, 7.0, 7.4, 7.6, 7.8, 8.1, and 8.2. At pH 7.5, the log K _{ow} values of five components in tall oil were 3.5, 4.2, 4.5, 4.7, and 5.4.
<u>Data Quality</u>	Reliable without restrictions – Klimisch Code 1a Note: the various K _{ow} values reflect the components in the mixture and not the mixture <i>per se</i> .
<u>References</u>	Dybdahl, H.P. 1993. Determination of log P _{ow} for single components in distilled tall oil. GLP Study No. 408335/475. Water Quality Institute, Horsholm, Denmark.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil pitch
CAS #	8016-81-7
Remarks	This substance is referred to as tall oil pitch in the test plan for tall oil and related substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Tall oil pitch was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. As a reference substance, a mixture of seven materials was used.
<u>Results</u>	At pH 2, the log P _{ow} [K _{ow}] values of three components in tall oil pitch were 4.3, 6.0, and 6.9. At pH 7.5, the log P _{ow} values of three components in tall oil pitch were 2.8, 3.6, and 4.4.
<u>Data Quality</u>	Reliable without restrictions – Klimisch Code 1a Note: the various K _{ow} values reflect the components in the mixture and not the mixture <i>per se</i> .
<u>References</u>	Dybdahl, H.P. 1993. Determination of log P _{ow} for single components in tall oil pitch. GLP Study No. 408335/473. Water Quality Institute, Horsholm, Denmark.

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Tall oil
CAS #	8002-26-4
Remarks	This substance is referred to as tall oil in the test plan for tall oil and related substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 D, "Ready Biodegradability: Closed Bottle Test"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1993
Contact time	28 days
Inoculum	Secondary effluent from Rungsted Treatment plant
Test conditions	<p>Inoculum: Secondary effluent was collected from Rungsted Treatment plant in Horsholm.</p> <p>Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes. After determination of the chemical oxygen demand, the solution was used within the same day.</p> <p>Test Setup: Test medium was prepared by adding 1 mL each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of approximately 9 mg O₂/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 1.96 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 5.01 mg O₂/L. Sodium benzoate, the reference compound, was added at 2 mg/L to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg O₂/L. Both the test and reference articles (1.96 mg/L and 2 mg/L) were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 8.35 mg O₂/L. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20°C. The study was performed in triplicate.</p> <p>Sampling frequency: Samples were collected for BOD analysis on days 0, 7, 14, 21, and 28.</p>

	<p>Controls: Yes.</p> <p>Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand for the added carbon sources was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds.</p>
<u>Results</u>	
Degradation % after time	43% after 7 days and 60% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate)
<u>Conclusions</u>	The biological oxygen demand for tall oil was 43 and 60% of the theoretical oxygen demand after 7 and 28 days, respectively. These data indicate that the material is dominated by readily biodegradable compounds. Tall oil did not inhibit the respiratory activity of the inoculum. The inoculum had satisfactory activity as demonstrated by more than 60% degradation within the 7 days using the reference compound.
<u>Data Quality</u>	Reliable without restrictions– Klimisch Code 1a
<u>References</u>	Madsen, T. 1993. Biodegradation of distilled tall oil. GLP Study No. 308067/475. Water Quality Institute, Horsholm, Denmark.

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Tall oil
CAS #	8002-26-4
Remarks	This substance is referred to as tall oil in the test plan for tall oil and related substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 F, Manometric respiratory test for biological degradation
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1999
Contact time	28 days
Inoculum	Activated sludge from a municipal sewage treatment plant
Test conditions	<p>Inoculum: Activated sludge from the municipal sewage treatment plant in Reutlingen was washed twice with dechlorinated tap water and centrifuged at 3000 rpm for one minute.</p> <p>Concentration of test chemical: A stock solution of the test material (102.2 mg/L) was prepared.</p> <p>Test Setup: Mineral medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to make a total volume of 1 liter in deionized water. Six flasks were prepared: two of the test article in mineral medium with inoculum (24 mg/L); two of the mineral medium plus the inoculum (24 mg/L); one of the reference substance [sodium benzoate (98.5 mg/L)] with inoculum (24 mg/L); and one of the test article in water with sterilized medium.</p> <p>Sampling frequency: Samples were collected for analysis on days 14 and 28.</p> <p>Controls: Yes.</p> <p>Method of calculating oxygen demand: Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the flasks containing test and reference compounds.</p>
<u>Results</u>	
Degradation % after time	73% after 28 days (test article); 97% after 28 days (sodium benzoate)

<u>Conclusions</u>	Seventy-three percent of tall oil was biodegraded after 28 days indicating that the organic portion of the test material was inherently biodegradable.
<u>Data Quality</u>	Reliable without restrictions– Klimisch Code 1a
<u>References</u>	Aniol. S. 1999. Biological degradation, manometric respirometry test. STZ Project No. 04/99. Steinbeis-Transferzentrum Angewandte und Umwelt-Chemie, Reutungen.

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Tall oil pitch
CAS #	8016-81-7
Remarks	This substance is referred to as tall oil pitch in the test plan for tall oil and related substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 D, "Ready Biodegradability: Closed Bottle Test"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1993
Contact time	28 days
Inoculum	Secondary effluent from Rungsted Treatment plant
Test conditions	<p>Inoculum: Secondary effluent was collected from Rungsted Treatment plant in Horsholm.</p> <p>Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes followed by magnetic stirring for 24 hours at 20°C. The solution was filtered and, after determination of the chemical oxygen demand, the solution was used within one day.</p> <p>Test Setup: Test medium was prepared by adding 1 mL each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of approximately 9 mg O₂/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 186 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 4.56 mg O₂/L. Sodium benzoate, the reference compound, was added at 2 mg/L to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg O₂/L. Both the test and reference articles (186 mg/L and 2 mg/L) were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 7.90 mg O₂/L. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20°C. The study was performed in triplicate.</p> <p>Sampling frequency: Samples were collected for BOD</p>

	<p>analysis on days 0, 7, 14, 21, and 28.</p> <p>Controls: Yes.</p> <p>Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand for the added carbon sources was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds.</p>
<u>Results</u>	
Degradation % after time	36% after 7 days and 41% after 28 days (test article); 72% after 7 days and 94% after 28 days (sodium benzoate)
<u>Conclusions</u>	The biological oxygen demand for tall oil pitch was 41% of the theoretical oxygen demand after 7 days and did not increase during the 28 days of the experiment. These data indicate that the material contains readily biodegradable and recalcitrant compounds. Tall oil pitch did not inhibit the respiratory activity of the inoculum. The inoculum had satisfactory activity as demonstrated by more than 70% degradation within the 7 days using the reference compound.
<u>Data Quality</u>	Reliable without restrictions– Klimisch Code 1a
<u>References</u>	Madsen, T. 1993. Biodegradation of tall oil pitch. GLP Study No. 308067/473. Water Quality Institute, Horsholm, Denmark.

ACUTE TOXICITY – ORAL	
<u>Test substance</u>	
Chemical Name	Tall oil
CAS #	8002-26-4
Remarks	This substance is referred to as tall oil in the test plan for tall oil and related substances.
<u>Method</u>	
Method/Guideline followed	Test procedure was similar to OECD Test Method 401, "Acute Oral Toxicity"
GLP (Y/N)	N
Year (Study Performed)	1986
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	5000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
<u>Result</u>	
Acute Oral LD ₅₀	>5000 mg/kg
<u>Detailed Summary</u>	
	Crude tall oil (CAS #8002-26-4) was administered orally (via gavage) to Sprague-Dawley rats (n = 5/sex/study) at 5000 mg/kg and the animals were observed for 14 days. The study was performed two times. Parameters evaluated included mortality, clinical signs, body weight gain, and gross pathology. In the first test, one male died on day 1 and a second male died on day 7. For the females, one death occurred on day 1 and a second on day 3. The overall mortality was 40%. No body weight effects were noted. Animals surviving the treatment appeared normal and exhibited no effects at gross pathological examination. In comparison, rats dying on study exhibited erosion of the stomach epithelium and hyperemia of the intestinal tract. When the study was repeated using the same dose level, no deaths occurred, the rats appeared normal throughout, no body weight effects occurred, and there were no gross pathological findings. Based on these data, the oral LD ₅₀ was greater than 5000 mg/kg.
<u>Data Quality</u>	
	Valid without restriction – Klimisch Code 1b
<u>Reference</u>	
	Prince, H.N. 1986. Acute toxicity report: oral toxicity. Report No. GBL 30373. Gibraltar Biological Laboratories, Inc., Fairfield, New Jersey.

ACUTE TOXICITY – ORAL	
<u>Test substance</u>	
Chemical Name	Tall oil
CAS #	8002-26-4
Remarks	This substance is referred to as tall oil in the test plan for tall oil and related substances.
<u>Method</u>	
Method/Guideline followed	Test procedure was similar to OECD Test Method 401, "Acute Oral Toxicity"
GLP (Y/N)	N
Year (Study Performed)	1986
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	6000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
<u>Result</u>	
Acute Oral LD ₅₀	>6000 mg/kg
<u>Detailed Summary</u>	
Crude tall oil (CAS #8002-26-4) was administered orally (via gavage) to Sprague-Dawley rats (n = 5/sex) at 6000 mg/kg and the animals were observed for 14 days. Parameters evaluated included mortality, clinical signs, body weight gain, and gross pathology. One female rat died on day 3; no other deaths occurred. All surviving animals appeared normal throughout the course of the study, and no body weight changes were observed. At gross pathology, no abnormalities were reported in the surviving animals; data for the animal dying on study were not presented. The oral LD ₅₀ was greater than 6000 mg/kg.	
<u>Data Quality</u>	
Valid without restriction – Klimisch Code 1b	
<u>Reference</u>	
Prince, H.N. 1986. Acute toxicity report: oral toxicity. Report No. GBL 30371. Gibraltar Biological Laboratories, Inc., Fairfield, New Jersey.	